

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

Plaintiff,

v.

SARDINHA SAUSAGE, INC., and
EDWARD SARDINHA,

Defendants.

04 } 11797 GAO

Civil No.

**PLAINTIFF'S MEMORANDUM IN SUPPORT
OF MOTION FOR PRELIMINARY INJUNCTION**

Introduction

This action seeks an injunction pursuant to the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 674, and the Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 467C, to prohibit the defendants' sale in commerce of meat and poultry products produced after the U.S. Department of Agriculture (USDA) suspended defendants' right to federal inspection services on April 15, 2004. An injunction is sought to immediately prohibit the sale in commerce of all meat and poultry products that lack USDA approval and to require the defendants to sell meat and poultry products only in compliance with the FMIA, the PPIA and the pertinent USDA regulations. Immediate relief is necessary in order that consumers will be protected from meat products produced under substandard conditions.

As shown below, the defendants have sold uninspected wholesale meat and poultry products, namely pork and chicken sausages and pork chourico meat, on a number of occasions to retail grocery establishments such as Shaw's supermarkets and Trader Joe's,

in violation of federal law since USDA suspended inspection of their facility.

The Legal Landscape

Meat and poultry food products in commerce for human use are required to be USDA inspected and meet USDA standards for safe and sanitary manufacture. FMIA, 21 U.S.C. §§ 604-606; PPIA, 21 U.S.C. § 455-56.¹ If they have been inspected and approved by USDA as meeting USDA standards, the products are labeled with the USDA stamp of approval. 21 U.S.C. § 604, 606. USDA inspectors are required to examine and

¹ Although "in commerce" is defined by the FMIA and PPIA as interstate commerce, 21 U.S.C. § 601(h), USDA enforces federal inspection law with respect to intrastate commerce in the Commonwealth of Massachusetts pursuant to designation under 21 U.S.C. §§ 454(c)(1) and 661(c)(1). The FMIA and the PPIA require each state to develop and maintain inspection programs that impose requirements at least equal to the federal inspection system. If the Secretary of Agriculture, in consultation with the state's Governor, determines that the state is not effectively enforcing requirements at least equal to those imposed by federal statute, the Secretary is required to designate that state as a state in which particular sections of the federal Acts apply to intrastate operations as well as interstate operations. The Governor of the Commonwealth of Massachusetts notified USDA that Massachusetts would not continue to operate a poultry and meat inspection program after January 11, 1976, and requested that USDA assume responsibility for carrying out the inspection provisions of the Acts. Thereafter, Massachusetts was designated as a state in which the federal USDA inspection requirements would apply to intrastate commerce. 40 Fed. Reg. 240 (Dec. 12, 1975) 57807-08. The particular sections designated as not being adequately enforced are 21 U.S.C. §§ 445-59, 461-467D, 601-24, and 671-90. Accordingly, commerce involving meat and poultry wholly within the Commonwealth of Massachusetts is subject to USDA inspection as if in interstate commerce.

The purpose of the inspection requirements is set forth in the Federal Meat Inspection Act as follows: "It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this Act are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this Act are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers." 21 U.S.C. § 602.

inspect all meat and poultry products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment. 21 U.S.C. §§ 605, 455. USDA inspectors also examine the “sanitary conditions of all establishments in which meat products are prepared.” 21 U.S.C. §§ 621, 456(a). If the inspectors find that the meat products are “not adulterated,” the products are labeled as “inspected and passed.” 21 U.S.C. §§ 606, 621, 456. “Adulterated” is defined as, among other things, meat and poultry that “has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” 21 U.S.C. §§ 601(m)(4), 608, 453(g)(4), 456. Sale of adulterated meat and poultry products that are unapproved by USDA is prohibited. 21 U.S.C. §§ 606, 610(c), 458. Meat and poultry products that have not been approved by USDA are “misbranded” if their labeling bears the USDA seal; 21 U.S.C. § 607(d), 610(c), 453(h), 458(c); and their sale is prohibited. 21 U.S.C. § 610, 456.

In connection with determining whether meat and poultry products are “not adulterated,” the USDA FSIS conducts monitoring activities in meat and poultry plants to examine whether production is sanitary and potential food safety hazards are identified and eliminated. Safian Decl. § 3. FSIS inspectors cannot determine that a product is “not adulterated” if the plant’s sanitation and food safety control system are not properly controlled, not properly monitored, not implemented, or are inadequate, or where establishments are not recording and maintaining records relative to the implementation of their sanitation and food safety systems. If the meat and poultry products are to pass USDA inspection, the plant must meet sanitation, facility, and operational standards, and have preventative systems in place to ensure production of constantly safe and unadulterated food, including production from animals that are free of disease. *Id.* See,

generally, 21 U.S.C. §§ 603-619, 454-465.²

At the center of the USDA inspection program are specific regulatory standards that meat and poultry product facilities are required to meet, the Sanitation Performance Standards (“SPS”) (9 C.F.R. §§ 416.1 – 416.6), the Sanitation Standard Operating Procedures (“SSOP”) (9 C.F.R. §§ 416.11 – 416.17), and the Hazard Analysis and Critical Control Point (“HACCP”) systems (9 C.F.R. §§ 417.1 – 417.8). These rules require, generally, that all federally inspected meat and poultry slaughter and processing establishments implement effective sanitation and process control systems to address food safety hazards that are reasonably likely to occur in their operations and ensure that products are produced in a sanitary environment, free from filth, pathogens, and other contaminants that could render the products adulterated or otherwise unsafe for consumers. Declaration of William J. Smith, USDA FSIS Assistant Administrator, Office of Field Operations (hereafter, Smith Decl.), §§ 3-4.³ USDA is required to approve only those meat and poultry products that have not been prepared, packed, or held under insanitary conditions whereby the products may have become contaminated with filthy or otherwise may be injurious to health. See 21 U.S.C. §§ 601(m), 608, 453(g), 456. As noted, USDA may approve a product only if it has been determined to be not adulterated. 21 U.S.C. §§ 456, 608. Smith Decl. § 6. USDA can make this

²USDA is authorized to make rules and regulations setting national standards for meat and poultry inspection. 21 U.S.C. §§ 603, 621, 456.

³ Raw meat products are known to contain pathogenic microorganisms, such as *Salmonella*, *Campylobacter*, *Escherichia coli* O157:H7, and *Listeria monocytogenes*, that can cause foodborne illness (symptoms of gastroenteritis, fever, headache, flu-like symptoms, body ache, and loss of balance to convulsions, miscarriage, and death) if they are not destroyed by an adequate cooking or other processing. Smith Decl. § 4. Ready-to-eat products, which are consumed without cooking at home, present concerns regarding pathogenic contamination, with *Listeria monocytogenes* being of particular risk. Smith Decl. § 4.

President of the business. See Declaration of Scott C. Safian, USDA Food Safety and Inspection Service (FSIS), Director of Evaluation and Enforcement Division, § 9 (hereafter, Safian Decl.) § 7.

On April 15, 2004, FSIS suspended inspection operations at Sardinha. This action was based on documented food safety and sanitation violations, which included repeated noncompliance with the Agency's SSOPs, SPAs, HHCCPs and the newer *Listeria monocytogenes* requirements. Safian Decl. § 9 and attachment 3.⁴ Smith Decl. §§ 14, 16. The violations included the failure of the plant to sanitize its production, direct contamination of ready-to-eat sausage by dripping condensation from unsanitary overhead refrigeration units, packing of ready-to-eat sausage in raw meat areas, and inadequate recordkeeping and improper testing, sampling and collection methods for *Listeria monocytogenes*. Smith Decl. § 14.

After USDA inspection was suspended, the defendants continued to produce meat and poultry products in commerce. The labeling provided by the defendants had the USDA stamp of approval. Safian Decl. §§ 10-11. On or about May 4, 2004, defendants delivered non-USDA approved pork chourico meat to Shaw's Supermarket, Fall River,

⁴ Previously, in February 2000, USDA FSIS had temporarily suspended inspection of the defendants' plant because of serious, persistent and recurring insanitary conditions and food safety system lapses. Smith Decl. § 19. On February 28, 2001, the FSIS had issued a Notice of Warning to the defendants after it established that they had violated the FMLA by purchasing and offering for sale uninspected meat products such as chourico meat pies and meat turnovers and offered the products for sale to customers with the USDA mark of inspection. Safian Decl. § 7 and attachment 1. On February 25, 2002, the FSIS issued another Notice of Warning to the defendants after establishing that Sardinha's had violated the PPLA by shipping uninspected product with labels bearing the marks of Federal inspection to be applied at the retail stores. Safian Decl. § 8 and attachment 2. On October 10, 2003, the FSIS notified the defendants that they had failed to implement controls for *Listeria monocytogenes*. Smith Decl. § 17. On December 18, 2003, the FSIS withheld USDA approval for certain ready to eat products when the defendants failed to address noncompliance with the *Listeria monocytogenes* regulations. Smith Decl. § 18.

determination only if a facility's sanitation and food safety control system is properly controlled, properly monitored, and the facility is recording and maintaining records to demonstrate its sanitation and safety systems. Smith Decl. § 6. The food safety regulations require the facility to demonstrate its sanitation and food safety control.

Most recently, the USDA FSIS has established new rules for federally inspected plants regarding the "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products." See 68 Fed. Reg. 34207 (June 6, 2003). The regulation requires that meat facilities producing certain ready-to-eat products, such as defendants', prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. Smith Decl. § 5. Facilities that produce ready to eat products exposed to the environment after processing and that support the growth of Lm. are required to address appropriate controls to prevent adulteration by *Listeria monocytogenes* in the plant's HACCP or SSOP systems or through a prerequisite program because *Listeria monocytogenes*, as well as other pathogenic microorganisms, can cause foodborne illness if they are not destroyed by an adequate lethality process. Smith Decl. § 4.

Statement of Facts

Sardinha's Sausage, Inc., is in the business of preparing and selling meat and poultry products, including raw and ready-to-eat products such as marinated pork, raw marinated poultry, fully cooked pork chourico, fully cooked chicken chourico, fully cooked pork linguica, fully cooked turkey linguica, and fully cooked franks. Smith Decl. §§ 8, 15. This type of business is required by the FMIA and PPIA to operate under Federal inspection. Smith Decl. § 8. Sardinha's has operated under a grant of inspection from USDA since March 1991. Sardinha's offices and operations are located at 206 Brownell Street, Fall River, Massachusetts 02720. Id. Defendant Edward Sardinha is

Massachusetts, with labels bearing the marks of USDA approval. Safian Decl. § 12. On or about May 4, 2004, the defendants delivered non-USDA approved pork chourico meat to Shaw's Supermarket, Dartmouth, Massachusetts, representing that the meat was USDA approved. Safian Decl. § 13. On or about May 7, 2004, the defendants delivered non-USDA approved pork chourico meat to Shaw's Supermarket, Middletown, Rhode Island, representing that the meat was USDA approved. Safian Decl. § 14.

FSIS investigators visited the defendants' plant on May 10, 2004, and observed packing cases of pork chourico meat bearing the USDA stamp of approval. Safian Decl. § 15. Frank Couto, the defendants' production manager, acknowledged that the products had been produced after suspension of USDA inspection. Safian Decl. § 15. FSIS investigators met with defendant Edward Sardinha on May 17, 2004. At that time, Sardinha acknowledged selling pork chourico meat produced after USDA suspension of inspection that bore the USDA stamp of approval. Safian Decl. § 16. On May 18, 2004, the FSIS notified defendants that it intended to seek permanent withdrawal of USDA inspection services. Safian Decl. § 17. Thereafter, USDA received additional reports of shipments by defendants of uninspected product. Safian Decl. § 18. In or about June 14 and 18, 2004, defendants sold chicken chourico sausage bearing the USDA mark of approval to Trader Joe's East, Inc., Needham, Mass. Safian Decl. § 18.⁵

⁵ Trader Joe's East, informed the FSIS that it had received this product on a monthly basis. *Id.*

Argument

Standard for Injunction

The United States District Courts are granted “jurisdiction specifically to enforce, and to prevent and restrain violations” of the FMIA and the PPIA. 21 U.S.C. §§ 674, 467c.

In deciding whether to grant a statutory injunction on behalf of a federal agency, the court plays a somewhat different role than in suits between private parties. United States v. Mass. Water Res. Auth., 256 F.3d 36, 47 (1st Cir. 2001). Traditionally, to receive injunctive relief, the moving party must demonstrate: (1) threat of irreparable harm; (2) a favorable balance of the equities; (3) likelihood of success on the merits; and (4) that the injunction will be in the public interest. SEC v. Fife, 311 F.3d 1, 8 (1st Cir. 2002). However, where federal statutes grant district courts authority to enforce a statute, the court is not required to apply all of the traditional four-part inquiry for equitable relief. See Mass. Water Res. Auth., 256 F.3d at 47-48. In that case, irreparable injury flows from the violation proved, and is presumed. Id. at 51. It would be a “rare case” in which a violation of regulatory standards does not lead to an injunction if the responsible enforcement agency requests one. Id. at 66. The agency is required to establish likelihood of success on the merits for preliminary relief. See Fife, 311 F.3d at 8 (upholding an injunction against defendant investment company, even though the district court erred in failing to consider irreparable harm, because “the essential requirement – finding that the SEC is likely to succeed on the merits of its claim– was met”). And the agency must establish that the defendant’s violations are reasonably likely to recur. SEC v. Sargent, 329 F.3d 34, 39 (1st Cir. 2003). Reasonable likelihood of recurrence is assessed by several factors, the nature of the violations, including their egregiousness and whether the

violations were isolated or repeated, and whether defendants because of their occupation, are in a position to violate again. Id.

Equitable discretion should be exercised to secure prompt compliance with the law. Romero-Barcelo, *supra*, at 314-317; United States v. San Francisco, 310 U.S. 16, 30-31 (1940); United States v. Painesville, 644 F.2d 1186, 1190 (6th Cir. 1981). Although issuance of an injunction is not mechanically required in every case, “[c]ourts of equity cannot, in their discretion, reject the balance that Congress has struck in a statute. . . . Their choice (unless there is statutory language to the contrary) is simply whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all.” United States v. Oakland Cannabis Buyers’ Cooperative, 532 U.S. 483, 497 (2001), citing TVA v. Hill, 437 U.S. 153, 194 (1978).

Accordingly, the Court is to consider whether the government is likely to succeed on the merits of its allegations that defendants have violated the USDA statutes; SEC v. Fife, 311 F.3d at 8; whether there is a likelihood of recurrence of the violations, and whether issuance of an injunction against further violations would be in the public interest. Id.

A Preliminary Injunction is Warranted in this Case

The United States is likely to succeed on the merits in its action for injunction. On at least five occasions since USDA suspended its inspectors from the Sardinha plant, defendants sold meat and poultry products to retail establishments. The occasions, May 4, 2004 (two instances on this date), May 7, June 14, and June 18, 2004, were fully documented after the fact by USDA inspectors. See Safian Decl. §§ 12 – 18. On each occasion, Sardinha falsely labeled the products with the USDA stamp of approval. In

addition to documentation of sales after the USDA suspension, Sardinha's production manager, Frank Couto, admitted to USDA inspectors, May 10, 2004, that the plant had continued to manufacture meat products after the suspension. Edward Sardinha made the same admission again to USDA on May 17, 2004. On May 18, 2004, USDA notified defendants that USDA intended to institute administrative proceedings to seek permanent withdrawal of federal inspection from the plant. Even after that event, Sardinha sold uninspected products in commerce.

The USDA suspension of inspection on April 15, 2005, was not the first inspection of troublesome conduct by defendants. USDA suspended inspection only after a number of serious and recurring lapses in sanitation and food safety controls. As noted, USDA had suspended inspection at the plant in February 2000; it had issued warning Notices to defendants in 2001, 2002, and 2003 about defendants' shipment of uninspected meat products. In October 2003, USDA notified defendants that defendants had failed to institute production controls for *Listeria monocytogenes*, a serious pathogen that can easily occur in unsanitary production facilities. And in December 2003, USDA refused to approve some ready-to-eat meat products because defendants had failed to institute *Listeria* controls. See footnote 4.

The issuance of an injunction is necessary at this time to protect consumers from meat and poultry processed by defendants without sanitation guarantees. USDA's forceful steps to prevent distribution of such products have been unsuccessful. The USDA statutes confer no other non-criminal options, as they do not provide for imposition of civil penalties.

The United States has established the elements for issuance of a preliminary injunction. First, there is a clear threat of irreparable harm if an injunction is not issued.

Absent an injunction, the defendants will likely continue to produce and sell their products in violation of the FMIA and PPIA. Defendants' violative conduct has recurred over a substantial period of time and defendants have been aware that their conduct violated the law but continued their conduct anyway. Defendants have continued their violative conduct even though their lack of production safety controls present a health risk to their customers. In view of the pattern of violations and defendants' continuing indifference to USDA regulations, immediate relief is needed to deter continued sales.

The statutory schemes established by Congress in the FMIA and the PPIA reflect a legislative determination that meat and poultry products that lack appropriate USDA approval are not safe for sale and consumption and therefore shall not be sold or transported in commerce. This Court ought not second-guess this balance that Congress has struck between public health and the commercial needs of meat producers. See United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. at 497.

For essentially the same reasons, the balance of the equities favors the issuance of an injunction, and an injunction will be in the public interest. Protecting the safety of consumers of meat and poultry products from adulterated or misbranded products plainly outweighs the interest of the defendants in continuing to produce and sell their products. USDA inspection is designed to detect hazards to poultry and meat that could cause injury to consumers. For example, meat that has not been properly handled or processed could be contaminated with trichinae, salmonella and other disease-causing bacteria. Meat that is not refrigerated properly is an excellent medium for the rapid growth of bacteria that can cause disease, and, occasionally, human fatalities. These important considerations are of prime importance to the health of consumers and they outweigh whatever inconvenience defendants may experience in instituting and maintaining USDA production requirements.

Moreover, all companies that sell poultry and meat food products are required to and do comply with USDA inspection, and those companies deserve a fair playing field upon which to compete. If they invest money and ongoing vigilance in complying with USDA rules and regulations, they are entitled to be confident that their competitors are required to do the same.


CONCLUSION

For the foregoing reasons, plaintiffs request that this Court issue a preliminary injunction prohibiting defendants from sale, transportation, and holding for sale or transportation, any meat or poultry products for human use.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

By:


ANITA JOHNSON
Assistant U.S. Attorney
Suite 9200, Moakley U.S. Ct hse
One Courthouse Way
Boston, Mass. 02210
617-748-3282

DATED: August 17, 2004